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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	MARKWELL-040	3546

23869 7590 11/27/2002

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EXAMINER

NASSER, ROBERT L

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/27/2002

*Remailed*  
*1-16-03*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/447,227**

Applicant(s)  
**Shults et al**

Examiner  
**Robert Nasser**

Art Unit  
**3736**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 19, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-24 and 28-42 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-24, 28-36, and 38-42 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Claims 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 now recites the accurate monitoring for a period exceeding about three weeks. Applicant points to page 33 to support this limitation. The examiner notes that page 33 states that the start up period (the first three steps) take up to three weeks, after which time accurate monitoring begins. This is not the same as the claim limitation. Therefore, this limitation constitutes new matter. Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 28, 32-36 and 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Picha. In figure 8, Picha shows a wholly implantable glucose sensor having an outer foam, non-smooth, layer which promotes tissue ingrowth and vascularization, to anchor the device in place.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24, 28, 30 and 32 are rejected under 35 U.S.C. 103(a) as being obvious over Priedel et al in view of Picha. Priedel teaches an implantable glucose in a host where the implantation is for a period of over 360 days (see column 1, lines 19 and 20 in combination with column 1, lines 44 and 45). It does not hold the device in place by tissue ingrowth. Picha teaches that a foam layer to promote ingrowth and anchor the device extends the life of implantable device. Hence, it would have been obvious to modify Priedel to use an outer foam layer like that of Picha, to extend its useable life.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Picha et al. It is well known to calibrate an implantable sensor prior to implantation.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Picha in view of Ward et al. Picha does not use telemetry to transmit the signal out of the body. However, Ward is one of a myriad references that teach that such is a known transmission technique. Hence, it would have been obvious to modify Priedel to use telemetry, as it is merely the substitution of one known equivalent for another.

Claim 37 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed 11/19/2002 have been fully considered but they are not persuasive.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser Jr. whose telephone number is (703) 308-3251. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg, can be reached on (703) 308-3130. The fax phone number for this Group is (703) 308-0758.

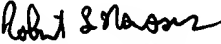
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [[max.hindenburg@uspto.gov](mailto:max.hindenburg@uspto.gov)].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

RLN

November 24, 2002

  
ROBERT L. NASSER  
PRIMARY EXAMINER